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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,176	02/01/2001	Michael J. Ackerman	07039-234001	7283

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EXAMINER

KHAN, OMAR A

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,176

Applicant(s)

ACKERMAN ET AL.

Examiner

Omar A Khan

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 and 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Claims 16-21, and 28-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15, and 22-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is incomplete for omitting a method step to determine or extract the T wave morphology from signals representative of electrical activity of the heart.

Claim 5 is vague and indefinite for citing the limitation "selected to achieve" which does not positively recite the method step. Examiner suggests –selecting the amount of said chemical stressor...-. Claim 5 recites the limitation "the amount". There is insufficient antecedent basis for this limitation in the claim. Examiner suggests –an amount- or that claim 5 depend from claim 2.

Claim 7 is vague and indefinite for citing the limitation "obtained" which does not positively recite the method step of the claimed invention. Examiner suggests –obtaining said electrical signal from precordial lead V4-.

Claim 8 is vague and indefinite for citing the limitation "generated" which does not positively recite the method step of the claimed invention. Examiner suggests –generating said electrical signals into an electrocardiogram-.

Claim 9 is vague and indefinite for citing the limitation "monitored" which does not positively recite the method step of the claimed invention. Examiner suggests – monitoring a heart rate of said individual-. Further, Claim 9 recites the limitation "the heart rate". There is insufficient antecedent basis for this limitation in the claim. Examiner suggests –a heart rate-.

Claims 10 and 12 are incomplete for omitting a method step to determine or extract the T wave morphology from signals representative of electrical activity of the heart.

Claim 22 cites the limitations "a programmable processor" and "T wave morphology" which are inferentially included and not positively recited in the claims.

Claim 23 recites the limitation "the repolarization interval". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1, 7-10, 12, 14, 15, 21 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kunig (US Patent No 4,622,980).

4. Claims 1, 7-10, 12, 14, 15, 21 and 22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Ekwall (US Patent No 6,016,443).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-6, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekwall (or Kunig) in view of Ben-Haim (US Patent No 6,285,898). Ekwall (or Kunig) discloses all of the claimed limitations but does not speak explicitly to chemically stressing the patient. Ben-Haim teaches a method of detecting cardiovascular disease having a chemical stressing

means for providing a stress test indicating cardiac health when an exercise stress test is not possible. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and apparatus of determining stress of a subject of Ekwall (or Kunig) and provide for chemically stressing the patient as taught by Ben-Haim for providing a stress test indicating cardiac health when an exercise stress test is not practical.

6. Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekwall (or Kunig). Ekwall (or Kunig) discloses all of the claimed limitations but does not explicitly speak to eliminating ectopic beats, calculating the maximal value rms differences, filtering the electrical signal, removing baseline fluctuation, and normalizing the rms differences to signal-averaged QRS complexes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and apparatus of determining a stress condition of a patient of Ekwall (or Kunig) to include eliminating ectopic beats, calculating the maximal value rms differences, filtering the electrical signal, removing baseline fluctuation, and normalizing the rms differences to signal-averaged QRS complexes since it was well known in the art to use such signal processing techniques to remove noise and increase the signal to noise ratio in the electrical signals for providing a more accurate representation of the true state of the patient and preventing potentially harmful, unwarranted therapy from being delivered to the patient.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Omar A Khan whose telephone number is (703) 308-0959. The examiner can normally be reached on M-F 9AM-6PM.

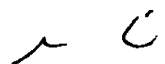
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.


11/13/02

Omar A Khan
November 13, 2002


GEORGE R. EVANISKO
PRIMARY EXAMINER
11/14/02